CLAIMS

1 A polymeric material incorporating an infection resistant biguanide compound pendant to the polymer chain, being chemically bound thereto through some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound, and the said chemical binding to secondary amine nitrogen atoms is by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage.

2 A polymeric material according to claim 1 wherein the biguanide compound is the residue of chlorhexidine or polyhexanide.

3 A medical device comprising a polymeric material incorporating an infection resistant biguanide compound pendant to the polymer chain, being chemically bound thereto through some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound, and the said chemical binding to secondary amine nitrogen atoms is by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage.

4 A medical device according to claim 3 wherein the biguanide compound is a residue of chlorhexidine or polyhexanide.

5 A medical device according to claim 3 or claim 4 wherein the medical device is formed from or coated with the polymeric material incorporating the infection resistant biguanide compound, or the medical device is first formed from or coated with polymeric material which is thereafter chemically bound to some but not all of the nitrogen atoms of the infection resistant biguanide compound, or the medical device is first formed from or coated with polymeric material which is thereafter chemically bound to the residuum of a non-polymeric compound that has been bound to some but not all of the nitrogen atoms of the infection resistant biguanide compound.

6 A medical device according to any one of claims 3 to 5 formed as a contact lens or intra-ocular lens.

7 A method of making an infection resistant polymeric material according to claim 1 or claim 2 which comprises chemically binding reactive sites on a polymeric material with some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage..

8 A method according to claim 7 which comprises the preliminary step of forming a partial free base of the biguanide compound before binding the reactive sites with the nitrogen atoms.

9 A method according to claim 7 or 8 wherein the reactive sites comprise isocyanate, isothiocyanate, epoxide, acid chloride, acid anhydride, aldehyde, ketone or unsaturated sites.

10 A method according to claim 7 or 8 wherein the reactive sites comprise hydroxyl, carboxyl or amino groups and the binding to the nitrogen atoms is carried out in the presence of a carbonyl diimidazole or carbidomide coupling agent.

11 A method of making an infection resistant polymeric material which comprises modifying a polymer precursor by chemically binding some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage, with reactive sites on the polymer precursor, and thereafter converting the so modified polymer precursor to an infection resistant polymeric material by a method including a polymerisation step.

12 A method according to claim 11 which comprises the preliminary step of forming a partial free base of the biguanide compound before binding the reactive sites with the nitrogen atoms.

13 A method according to claim 11 or 12 wherein the reactive sites comprise isocyanate, isothiocyanate, epoxide, acid chloride, acid anhydride, aldehyde, ketone or unsaturated sites.

14 A method according to claim 11 or 12 wherein the reactive sites comprise hydroxyl, carboxyl or amino groups and the binding to the nitrogen atoms is carried out in the presence of a carbonyl diimidazole or carbidomide coupling agent.

15 A method according to any one of claims 11 to 14 wherein the polymer precursor also contains acrylate, methacrylate, allyl or vinyl groups, and the polymerisation step is carried out by polymerising the modified polymer precursor through the said groups.

16 A method of making an infection resistant polymeric material according to claim 1 which comprises modifying a non-polymeric compound by chemically binding some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage. an infection resistant biguanide compound with reactive sites on the non-polymeric compound, and thereafter chemically binding the so modified compound to a polymeric material.

17 A method according to claim 16 which comprises the preliminary step of forming a partial free base of the biguanide compound before binding the reactive sites with the nitrogen atoms.

18 A method according to claim 16 or 17 wherein the reactive sites comprise isocyanate, isothiocyanate, epoxide, acid chloride, acid anhydride, aldehyde, ketone or unsaturated sites.

19 A method according to claim 16 or 17 wherein the reactive sites comprise hydroxyl, carboxyl or amino groups and the binding to the nitrogen atoms is carried out in the presence of a carbonyl diimidazole or carbidomide coupling agent.

20 A method according to any one of claims 16 to 19 wherein the non-polymeric compound also contains acrylate, methacrylate, allyl or vinyl groups, and the modified compound is chemically bound to a polymeric material through the said groups.

21 A method according to any one of claims 7 to 20 wherein the resulting polymer containing biguanide groups is subsequently blended with other polymeric material to form an infection resistant polymer blend for use in forming an article of manufacture.

22 A method according to claim 21 wherein the resulting polymer containing biguanide groups is subsequently blended with medically acceptable polymeric material to form an infection resistant medical polymer blend for use in the manufacture of a medical device.

23 A method according to claim 22 wherein the resulting polymer containing biguanide groups is subsequently blended with ocularly acceptable lens material to form an infection resistant ocular polymer blend for use in the manufacture of a contact or intra-ocular lens.

24 A method according to claim 23 wherein the resulting polymer containing biguanide groups includes acrylate, methacrylate, allyl or vinyl groups, and the polymer is subsequently copolymerised with ocularly acceptable lens material to form an infection resistant ocular polymer for use in the manufacture of a contact or intra-ocular lens.

25 A method according to any one of claims 71 to 20 wherein the resulting polymer containing biguanide groups is subsequently coated on to an article of manufacture to form an infection resistant coating thereon.

26 A method according to any one of claims 7 to 25 wherein the biguanide compound is chlorhexidine or polyhexanide.

27 A method according to claim 26 wherein the resulting polymer contains biguanide groups derived from both chlorhexidine and polyhexanide.

32 A method according to any one of claims 11 to 27 wherein the resulting polymer containing biguanide groups is subsequently coated on to an article of manufacture to form an infection resistant coating thereon.

33 A method according to any one of claims 11 to 32 wherein the biguanide compound is chlorhexidine or polyhexanide.

34 A method according to claim 33 wherein the resulting polymer contains biguanide groups derived from both chlorhexidine and polyhexanide.

35 A polymeric material according to claim 1 substantially as hereinbefore described with reference to any of the specific Examples.

36 A method according to claim 11 substantially as hereinbefore described with reference to any of the specific Examples.

37 A method according to claim 16 substantially as hereinbefore described with reference to any of the specific Examples.

38 A method according to claim 22 substantially as hereinbefore described with reference to any of the specific Examples.

AMENDED CLAIMS

39. (New) A polymeric material incorporating an infection resistant biguanide compound pendant to the polymer chain, being chemically bound thereto through some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound, and the said chemical binding to secondary amine nitrogen atoms is by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage.

40. (New) A polymeric material according to claim 1 wherein the biguanide compound is the residue of chlorhexidine or polyhexanide.

41. (New) A medical device comprising a polymeric material incorporating an infection resistant biguanide compound pendant to the polymer chain, being chemically bound thereto through some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound, and the said chemical binding to secondary amine nitrogen atoms is by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage.

42. (New) A medical device according to claim 3 wherein the biguanide compound is a residue of chlorhexidine or polyhexanide.

43. (New) A medical device according to claim 3 wherein the medical device is formed from or coated with the polymeric material incorporating the infection resistant biguanide compound, or the medical device is first formed from or coated with polymeric material which is thereafter chemically bound to some but not all of the nitrogen atoms of the infection resistant biguanide compound, or the medical device is first formed from or coated with polymeric material which is thereafter chemically bound to the residuum of a non-polymeric compound that has been bound to some but not all of the nitrogen atoms of the infection resistant biguanide compound.

44. (New) A medical device according to claim 3 formed as a contact lens or intra-ocular lens.

45. (New) A method of making an infection resistant polymeric material according to claim 1 which comprises chemically binding reactive sites on a polymeric material with some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage.

46. (New) A method according to claim 7 which comprises the preliminary step of forming a partial free base of the biguanide compound before binding the reactive sites with the nitrogen atoms.

47. (New) A method according to claim 7 wherein the reactive sites comprise isocyanate, isothiocyanate, epoxide, acid chloride, acid anhydride, aldehyde, ketone or unsaturated sites.

48. (New) A method according to claim 7 wherein the reactive sites comprise hydroxyl, carboxyl or amino groups and the binding to the nitrogen atoms is carried out in the presence of a carbonyl diimidazole or carbidomide coupling agent.

49. (New) A method of making an infection resistant polymeric material which comprises modifying a polymer precursor by chemically binding some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH-biguanide group or groups of the infection resistant biguanide compound by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage, with reactive sites on the polymer precursor, and thereafter converting the so modified polymer precursor to an infection resistant polymeric material by a method including a polymerisation step.

50. (New) A method according to claim 11 which comprises the preliminary step of forming a partial free base of the biguanide compound before binding the reactive sites with the nitrogen atoms.

51. (New) A method according to claim 11 wherein the reactive sites comprise isocyanate, isothiocyanate, epoxide, acid chloride, acid anhydride, aldehyde, ketone or unsaturated sites.

52. (New) A method according to claim 11 wherein the reactive sites comprise hydroxyl, carboxyl or amino groups and the binding to the nitrogen atoms is carried out in the presence of a carbonyl diimidazole or carbidomide coupling agent.

53. (New) A method according to claim 11 wherein the polymer precursor also contains acrylate, methacrylate, allyl or vinyl groups, and the polymerisation step is carried out by polymerising the modified polymer precursor through the said groups.

54. (New) A method of making an infection resistant polymeric material according to claim 1 which comprises modifying a non-polymeric compound by chemically binding some but not all of the amine nitrogen atoms of the -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide compound by means of a substituted urea linkage, or a substituted thiourea linkage, or a N,N-disubstituted amide linkage, or a N,N-disubstituted hemiaminal or aminal linkage, or a tertiary amine linkage. an infection resistant biguanide compound with reactive sites on the non-polymeric compound, and thereafter chemically binding the so modified compound to a polymeric material.

55. (New) A method according to claim 16 which comprises the preliminary step of forming a partial free base of the biguanide compound before binding the reactive sites with the nitrogen atoms.

56. (New) A method according to claim 16 wherein the reactive sites comprise isocyanate, isothiocyanate, epoxide, acid chloride, acid anhydride, aldehyde, ketone or unsaturated sites.

57. (New) A method according to claim 16 or 17 wherein the reactive sites comprise hydroxyl, carboxyl or amino groups and the binding to the nitrogen atoms is carried out in the presence of a carbonyl diimidazole or carbidomide coupling agent.

58. (New) A method according to claim 16 wherein the non-polymeric compound also contains acrylate, methacrylate, allyl or vinyl groups, and the modified compound is chemically bound to a polymeric material through the said groups.

59. (New) A method according to claim 7 wherein the resulting polymer containing biguanide groups is subsequently blended with other polymeric material to form an infection resistant polymer blend for use in forming an article of manufacture.

60. (New) A method according to claim 21 wherein the resulting polymer containing biguanide groups is subsequently blended with medically acceptable polymeric material to form an infection resistant medical polymer blend for use in the manufacture of a medical device.

61. (New) A method according to claim 22 wherein the resulting polymer containing biguanide groups is subsequently blended with ocularly acceptable lens material to form an infection resistant ocular polymer blend for use in the manufacture of a contact or intra-ocular lens.

62. (New) A method according to claim 23 wherein the resulting polymer containing biguanide groups includes acrylate, methacrylate, allyl or vinyl groups, and the polymer is subsequently copolymerised with ocularly acceptable lens material to form an infection resistant ocular polymer for use in the manufacture of a contact or intra-ocular lens.

63. (New) A method according to claims 7 wherein the resulting polymer containing biguanide groups is subsequently coated on to an article of manufacture to form an infection resistant coating thereon.

64. (New) A method according to claim 7 wherein the biguanide compound is chlorhexidine or polyhexanide.

65. (New) A method according to claim 26 wherein the resulting polymer contains biguanide groups derived from both chlorhexidine and polyhexanide.